



DIVISION OF CARDIO-RENAL DRUG PRODUCTS
Joint Clinical Review

NDA: 20-297

Sponsor: Glaxo SmithKline

Submission: SE8-009 (27 September 2002): supplement requesting an indication for use of carvedilol in patients with left ventricular dysfunction after myocardial infarction.

Review date: December 17, 2002

Reviewers: N. Stockbridge, M.D., Ph.D., HFD-110

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In the original medical-statistical review for the Capricorn study, the reviewers expressed some concern about the discrepancy between the overall mortality result (which favors carvedilol) and the mean or median time to mortal event among subjects who died (which seems longer on placebo; see Table 10). While the observation is correct, the interpretation as a discrepancy is not.

If two survival curves separate late, as the curves do in Capricorn, then this outcome seems quite likely.

In summary, the medical and statistical reviewers find no compelling internal inconsistencies in the mortality data of Capricorn.